

# What if...

...your botulinum toxin brand was devoted to you and your patients?



EXPERIENCE A  
DIFFERENT FOCUS

A movement disorder partner highly committed to empowering you through appropriate support along with lasting cervical dystonia relief.<sup>1\*</sup>

\*In clinical trials, the primary endpoint for cervical dystonia was based on the total TWSTRS change at Week 4. A majority of adults with cervical dystonia did not need re-treatment until Weeks 14-18. However, some patients had a longer duration of response.<sup>1</sup>

TWSTRS=Toronto Western Spasmodic Torticollis Rating Scale.

## Indications

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Spasticity in patients 2 years of age and older
- Cervical dystonia in adults

..... ————— .....  
FDA APPROVED FOR  
adult cervical dystonia

## IMPORTANT SAFETY INFORMATION

### Warning: Distant Spread of Toxin Effect

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Please see additional Important Safety Information on pages 8-9 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

 **Dysport**®  
(abobotulinumtoxinA)

## JANICE

Lives in Greenbrier, TN

### MEDICAL HISTORY

Janice has been living with cervical dystonia (CD) for 29 years and has been taking Dysport for 8 years

- // Diagnosed with CD at age 30
- // First experienced symptoms (unexplained right-to-left movement of head) while expecting her first child at age 22
- // Symptoms subsided until she was pregnant with her second child 6 years later
- // When her symptoms got worse during her second pregnancy, she decided to look for answers and met with a neurologist



Janice, a real Dysport patient living with CD

### My cervical dystonia diagnosis

“ [By the time I was diagnosed,] the symptoms had progressed to a very obvious uncontrollable [head] movement...back and neck pain....[Being diagnosed] was a wonderful feeling, to have a name to go with my condition. I felt vindicated, in a sense. ”

### How this disease impacted me

“ I was a young woman with high expectations. I felt robbed of having control. ”

### How Dysport worked for me

“ [Dysport] has lived up to my expectations...it has been a reliable, effective treatment—it’s comforting to know that I can count on [it] to work for me. ”



Individual results may vary. Janice is the only Dysport patient in this image. Janice was compensated for her time.

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### Warnings and Precautions

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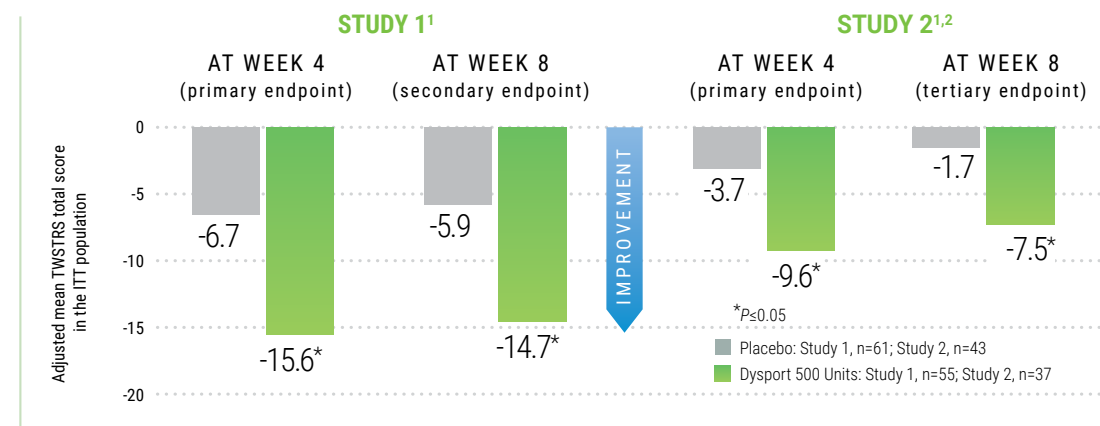


# Reduces symptoms backed by proven results

# Sustained relief beyond the minimum time to re-treatment

## Dysport significantly reduced abnormal head position at Week 4<sup>1,2</sup>

### Improvement from baseline at Week 4 in abnormal head position as measured by reduction in TWSTRS total score



**Study design:** The efficacy and safety of Dysport were evaluated in 2 randomized, double-blind, placebo-controlled, single-dose, parallel-group studies in treatment-naive CD patients. The primary efficacy endpoint in both studies was the reduction in severity of dystonia, patient-perceived disability from dystonia, and pain as measured by total change in the TWSTRS at Week 4. These studies were followed by long-term open-label extensions that allowed titration in 250 Unit steps to doses in a range of 250 to 1000 Units, after the initial dose of 500 Units. In the extension studies, re-treatment was determined by clinical need after a minimum of 12 weeks. The median time to re-treatment was 14 weeks and 18 weeks for the 75th percentile.<sup>1</sup>

## For most patients, Dysport provides improvement in range of motion that lasts beyond the minimum re-treatment time of 12 weeks<sup>1,2</sup>

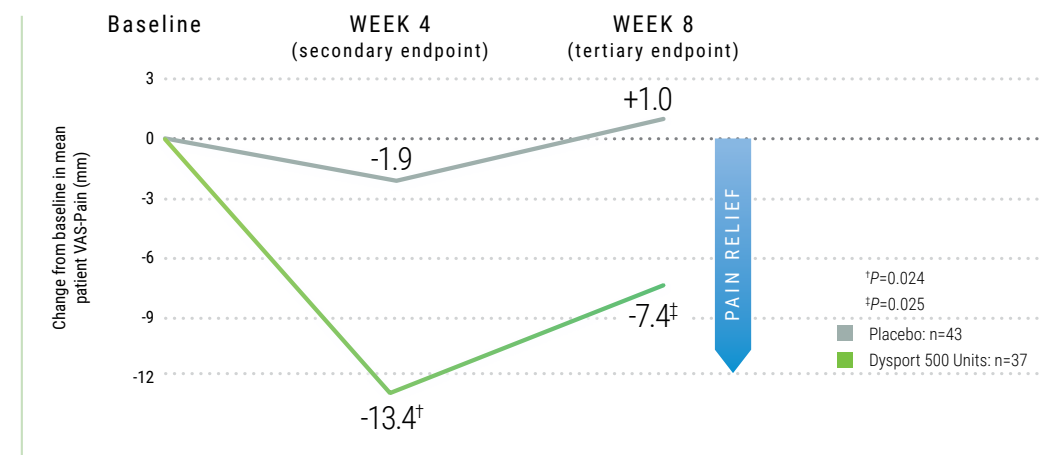
### Time to re-treatment



Time to re-treatment was not a primary endpoint. Repeat Dysport treatment should be administered no sooner than 12 weeks after the previous injection<sup>1</sup>  
 // In the pivotal trials for adult CD, need for re-treatment was determined by change in TWSTRS total score returning to within 10% of baseline<sup>2</sup>  
 // The median time to re-treatment was 14 weeks and 18 weeks for the 75th percentile<sup>1</sup>

## Dysport significantly reduced VAS neck pain at Week 4<sup>2</sup>

### Reduction from baseline in pain severity following 1 treatment dose



// Baseline mean VAS score (patient self-rated) was 48.6 in the Dysport group and 52.9 in the placebo group.<sup>2</sup>



“ I don't feel like I have waning symptom relief...[Dysport] has been a reliable, effective treatment that I have come to count on. ”

—Janice, a Dysport patient

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

#### Dysphagia and Breathing Difficulties

Treatment with Dysport and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant side effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.



ITT=intent-to-treat; VAS=visual analog scale.

## A wide dosing range allows you to customize subsequent doses based on patient response<sup>1</sup>

### Recommended dosage and administration for adults with CD<sup>1</sup>

	Recommended Dose Range in Dysport Units	
<b>TORTICOLLIS</b>		
Sternocleidomastoid*	50	350
Trapezius	50	300
Scalenus (medius and anterior)	50	300
<b>LATEROCOLLIS</b>		
Levator scapulae	50	200
Trapezius	50	300
Scalenus (medius and anterior)	50	300
<b>ANTEROCOLLIS</b>		
Sternocleidomastoid*	50	350
Scalenus (medius and anterior)	50	300
<b>RETROCOLLIS</b>		
Levator scapulae	50	200
Trapezius	50	300
Longissimus	100	200
Splenius capitis	75	450
Semispinalis capitis	50	250

\*Median dose: Dysport 125 Units.

### Additional Dosing Guidance<sup>1,3</sup>

1. Re-treatment of adult CD should not occur in intervals of less than 12 weeks.
2. The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products.
3. Doses up to Dysport 1000 Units (divided among affected muscles) were systematically evaluated. The recommended initial dose is Dysport 500 Units with titration in 250-Unit steps according to the patient's response.
4. The median dose for the sternocleidomastoid (SCM) was 125 Units.
5. Limiting the dose injected unilaterally into the SCM to Dysport 150 Units or less may reduce the occurrence of dysphagia.

## Safety results in 173 adult patients with CD receiving Dysport up to 500 Units<sup>1</sup>

### Most common adverse reactions (≥5%) and greater than placebo in the pooled, double-blind, placebo-controlled phase of clinical trials<sup>1</sup>

Adverse Reactions	Dysport 500 Units (n=173), %	Placebo (n=182), %
<b>Any adverse reaction</b>	61	51
<b>General disorders and administration site conditions</b>		
Injection site discomfort	13	8
Fatigue	12	10
Injection site pain	5	4
<b>Musculoskeletal and connective tissue disorders</b>		
Muscular weakness	16	4
Musculoskeletal pain	7	3
<b>Gastrointestinal disorders</b>		
Dysphagia	15	4
Dry mouth	13	7
<b>Nervous system disorders</b>		
Headache	11	9
<b>Respiratory, thoracic, and mediastinal disorders</b>		
Dysphonia	6	2
<b>Eye disorders<sup>†</sup></b>		
	7	2

To reduce the recurrence of dysphagia, limit the dose injected unilaterally into the sternocleidomastoid to 150 Units or less.<sup>1,3</sup> Use of simultaneous electromyography-guided application of Dysport may be helpful in locating these active muscles.<sup>1</sup>

<sup>†</sup>The following preferred terms were reported: vision blurred, diplopia, visual acuity reduced, eye pain, eyelid disorder, accommodation disorder, dry eye, eye pruritus.

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

#### Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of Dysport.

#### Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

#### Intradermal Immune Reaction

The possibility of an immune reaction when injected intradermally is unknown. The safety of Dysport for the treatment of hyperhidrosis has not been established. Dysport is approved only for intramuscular injection.

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## Most Common Adverse Reactions

**Adults with lower limb spasticity** ( $\geq 5\%$ ): falls, muscular weakness, and pain in extremity and with **upper limb spasticity** ( $\geq 4\%$ ): muscular weakness.

**Pediatric patients with lower limb spasticity** ( $\geq 10\%$ ): nasopharyngitis, cough and pyrexia and with **upper limb spasticity** ( $\geq 10\%$ ): upper respiratory tract infection and pharyngitis.

**Adults with cervical dystonia** ( $\geq 5\%$ ): muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders.

## Drug Interactions

Co-administration of Dysport and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport may potentiate systemic anticholinergic effects, such as blurred vision. The effect of administering different botulinum neurotoxins at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of Dysport.

## Special Populations

### Use in Pregnancy

There are no adequate and well-controlled studies in pregnant women. Dysport should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Based on animal data, Dysport may cause fetal harm.

### Pediatric Use

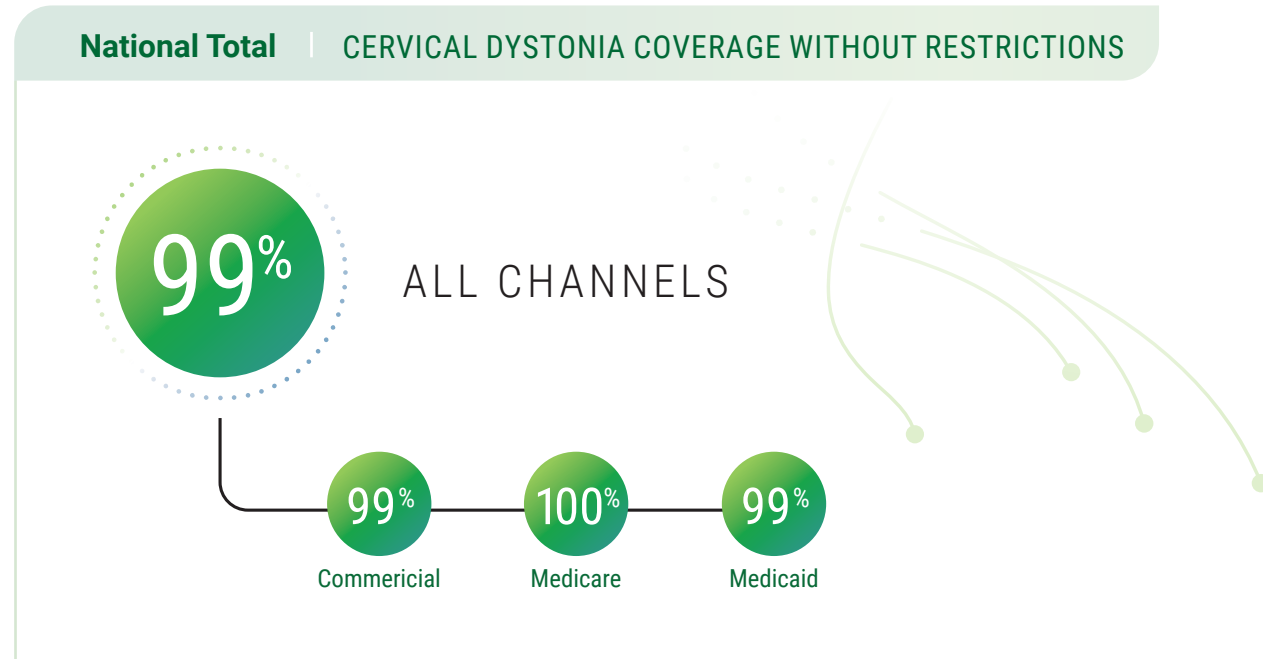
The safety and effectiveness of Dysport injected into proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established. Based on animal data Dysport may cause atrophy of injected and adjacent muscles; decreased bone growth, length, and mineral content; delayed sexual maturation; and decreased fertility.

### Geriatric Use

In general, elderly patients should be observed to evaluate their tolerability of Dysport, due to the greater frequency of concomitant disease and other drug therapy. Subjects aged 65 years and over who were treated with Dysport for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% vs. 6% and 4% vs. 2%, respectively).

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Nearly 100% of patient lives covered for the treatment of cervical dystonia



**The Copay Assistance Program: Assistance With Private Insurance Copay or Coinsurance Costs for Dysport**

- // In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000
- // IPSEN CARES® will confirm every 12 months that eligible\* patients meet the criteria for the program

As little as  
**\$0 PER PRESCRIPTION**  
for eligible\* patients

Annual maximum of \$5,000 per calendar year in copay assistance

To learn more,  
visit [IpsenCares.com](https://IpsenCares.com)

This document represents no promise or guarantee concerning coverage or levels of reimbursement. It is recommended that you contact your local payers with regard to local reimbursement policies and practices. Please consult your counsel or reimbursement specialist on reimbursement or billing questions specific to your practice.

Coverage data provided by Breakaway Partners and current as of February 2021.

\*Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients residing in Massachusetts, Minnesota, or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000.

Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or CoverMyMeds are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary.

**IMPORTANT SAFETY INFORMATION**

**Most Common Adverse Reactions**

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## EXPERIENCE A DIFFERENT FOCUS

Highly committed to empowering you through appropriate support along with lasting cervical dystonia relief.<sup>1</sup>



### Reduces symptoms backed by proven results

Significantly reduced abnormal head position ( $P \leq 0.05$ ) and relieved neck pain ( $P \leq 0.05$ ) vs placebo at Week 4<sup>1,2</sup>



### Relief between the time to re-treatment

Improvement in range of motion lasted beyond the minimum re-treatment time of 12 weeks, with a majority of patients not needing another injection for 14 to 18 weeks<sup>2</sup>



### A demonstrated, well-studied safety profile

The most common adverse reactions ( $\geq 5\%$ ) and greater than placebo were muscular weakness, dysphagia, dry mouth, injection-site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection-site pain, and eye disorders<sup>1</sup>



### Appropriate support for you and your patients

- // C.L.I.M.B.<sup>®</sup> online learning continuum with injection education and training
- // In-person, virtual, and on-demand peer-to-peer education
- // Clinical tools and patient materials
- // IPSEN CARES<sup>®</sup> patient coverage and access support<sup>1</sup>

SCAN HERE to access the Dysport Resource Catalogue or visit [DysportHCP.com/CatalogueCD](https://DysportHCP.com/CatalogueCD)



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**References:** 1. Dysport<sup>®</sup> (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020. 2. Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. 3. Hauser RA, Truong D, Hubble J, et al. AbobotulinumtoxinA (Dysport) dosing in cervical dystonia: an exploratory analysis of two large open-label extension studies. *J Neural Transm.* 2013;120(2):299-307.



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